Center for AIDS Research
Fall 2017 Request for Applications - Clinical and Translational Pharmacology Proposals

APPLICATION DEADLINE: May 30th, 2017 by 5 PM EST

Purpose

To support focused, highly innovative research projects and pilot studies that utilize the CFAR Pharmacology Shared Resource to address key gaps in our understanding of HIV/AIDS pharmacology and therapeutics and that **address the NIH HIV/AIDS High Priority Research Topics** that have been designated by National Institutes of Health (NIH) and Office of AIDS Research (OAR) (see attached list). More information about the CFAR Pharmacology Shared Resource can be found at the end of this document.

Background

The mission of the CFAR is to provide leadership, services and infrastructure necessary to: establish multidisciplinary collaborations that achieve high-impact discoveries; support the early career development of diverse young HIV/AIDS investigators; and to establish a distinctive scientific identity, placing the University of Rochester at the forefront of HIV/AIDS research.

Scientific Areas of Interest

This RFA is intended to support pilot awards that address one of these four scientific areas of interest. These include:

- **HIV, antiviral pharmacology and drug development:** Although there are numerous approved antivirals for HIV and HCV, drug development research has continued with active areas of research that include: new drug assay development, long-acting antiretrovirals for prevention, treatment and viral reservoir eradication, compartmental ARV penetration, point of care pharmacology tests and medication adherence technology. In addition, new formulations of tenofovir (e.g. TAF) result in targeted delivery to key cellular targets and suggest that additional research is needed related to long-term antiviral tolerance. The emergence broadly neutralizing monoclonal antibodies has created a new class of antiretroviral proteins that is currently undergoing pre-clinical and clinical investigation. These antibodies require pharmacologic investigation to determine optimal dosing schedules, formulations and compartmental distribution. New analytical strategies for quantitation of drug concentrations in various biological specimens and reservoirs, identification of biomarkers of response, and novel physiological-based pharmacokinetic models are needed to characterize mechanisms of antiviral success and failure.

- **HIV, antiviral pharmacology and drug interactions research:** The continued evolution in HIV treatment and need for lifelong therapy has led to an ongoing need to determine clinically relevant pharmacokinetic drug interactions in therapeutic areas that include cardiovascular, neurologic, bone, behavioral, contraceptive as well as others. The safe and effective use of antivirals requires that drugs used for these co-morbidities be investigated with antivirals and that dosage requirements for medications that are prescribed for these indications be evaluated.

- **HIV pharmacology and Cure:** Ongoing research that is focused on viral reservoirs and eradication that may lead to a cure currently is focused on strategies that activate latent virus and/or optimize ARV penetration into protected compartments. In addition, immune modulation that id directed at viral replication that follows latency activation is also a focus of active investigation. There are multiple aspects of pharmacokinetics and pharmacodynamics that may be addressed as these new approaches are investigated.

- **HIV pharmacology and HCV/HBV Co-Infection, Tuberculosis and End-Organ/Inflammation:** The emphasis of the NIH HIV Research Networks on viral hepatitis, tuberculosis and chronic inflammation has led to many new therapeutic strategies in each of these areas. These medications require rigorous pre-clinical and clinical pharmacology testing for optimal dosages, dosage formulations, compartmental distribution changes and drug interactions. The interplay of pharmacokinetics, pharmacodynamics and pharmacogenomics for these new therapeutic strategies is also needed.

Eligibility

This is a collaborative application that should include Co-PI's from both University of Rochester and University at Buffalo. The submitting Co-PI must hold a faculty appointment (not adjunct) at University of Rochester.

- University of Rochester and University at Buffalo Professors, Associate Professors, Assistant Professors, or Research Assistant Professors.
- The submitting Co-PI must hold a faculty appointment (not adjunct) at University of Rochester.
- **Please note: There are very specific restrictions for T32 awardees regarding eligibility to work on CFAR Pilot awards and eligibility must be reviewed prior to submitting the application. K awardees are not eligible to receive salary support from a CFAR pilot award. Please contact Laura Enders for further information about T32 recipients and K awardees eligibility on a project before submitting the application.**

Projects will receive the highest priority if they*:*

- Utilize the currently validated drug assays and established pharmacokinetic models of the UR Pharmacology Shared Resource.
- Have strong potential for follow up funding by NIH or other funders.
- Are interdisciplinary and create new collaborations involving multiple departments.

Awards

Up to 3 awards will be made for up to a 9-month period with maximum funding of **$10,000** in Direct Costs. Costs are for sample collection and related costs. Salary for PI's is not permitted. **Earliest start date is 8/1/17. End date must be 4/30/18. Please contact Laura Enders prior to submission if this proposal will include a component at University of Buffalo to discuss budget requirements.**

Application Instructions

Applications must be submitted to Laura Enders (Laura_Enders@urmc.rochester.edu), before or on **May 30th, by 5 PM EST.** Applicants are to submit the application electronically as a single file attachment in pdf format.

Application Requirements

The items required for the submission are listed in the CFAR checklist below. A copy of the checklist that indicates which items are being submitted should be included in the application. A printable CFAR Checklist is located at the end of the application before the CFAR Grant Cover Sheet.

CFAR Checklist: (to be submitted in one combined PDF)

- ☐ Completed CFAR Proposal Checklist indicating submitted items (see bottom of these guidelines for printable version) and indicating PI or CO-I at each institution.
- ☐ CFAR Proposal sign-off form (see bottom of these guidelines for printable version)
- ☐ Draft Cost Sharing form signed by PI and department (fully signed forms will be required for pilots selected for funding). See UR ORPA website for the form. Contact Laura Enders for more information or a blank form.
- ☐ CFAR Grant Cover Sheet - Modified PHS 398 face page (see last page of these guidelines)
- ☐ Abstract
- ☐ Identification of the **CFAR RFA Research Topic** that this application will focus on (see RFA Specific Areas of Interest)

☐ Identification of the **High Priority Research Topic** that this application will focus on (see the attached NIH HIV/AIDS Research Priorities list as designated by NIH and OAR included in these guidelines)

☐ NIH-format biosketch for PI, co-investigators and mentors

☐ Updated Other Support for PI's only

☐ Research Plan (limited to 3 pages):

The Research Plan consists of items noted below, as applicable. It should be self-contained and include sufficient information to evaluate the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.

- Specific Aims
- Research Strategy (Significance, Innovation and Approach)
- Timeline
- Source of samples

☐ Human Subjects and Animals (no limit):

The Human Subjects and Animals Plan consists of items noted below, as applicable. It should be self-contained and include sufficient information to evaluate the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.

- Protection of Human Subjects
- Vertebrate Animals

☐ Plans for Future Funding (limited to 1 page):

- Provide a short outline of how the pilot will develop into a NIH-funded grant. It should include the proposed hypothesis and specific aims intended for a NIH grant application as well as the projected timeline for submission.

☐ Pharmacology Shared Resource Request Sheet (see bottom of these guidelines)

☐ Data Analysis Plan (half-page limit):

- Provide a brief data analysis plan and identify if bioinformatics support is needed for data collection and management.

☐ Mentoring Plan (if applicable):

- Identify a primary mentor and provide a clearly delineated mentoring plan, including frequency and methods. The plan should identify long-term needs and goals in order to establish a successful independent academic career within the next 2 to 5 years.

☐ Budget (limited to 1 page using PHS 398 Form Page 4, providing a detailed description of supplies and other expenses within the form page):

- Limited to **$10,000** direct costs.
- Earliest start date 8/1/17, end date must be 4/30/18.
- Unless exceptional circumstances, funds may not be used to support faculty salary but the budget must identify the proposed effort.
- Funds may not be used for travel to professional meetings or equipment.
- Funds may be used to support research supplies and expenses, travel to collect data and other non-faculty salary.
- If applicable, identify other sources of support that will be used to complete the pilot project.

☐ Bibliography

Submission and Review Process

This is an internal competition for NIH-funds already awarded to the CFAR. **ORPA review and sign-off is not required but departmental review and approval should be sought through the CFAR sign-off form.** Proposals will be reviewed by a faculty committee and will be assigned a priority score in accordance with these 6 categories**:**

- Significance (including scientific premise and hypothesis)
- PI, Scientific Team & Environment
- Innovation and Multidisciplinary Approach
- Experimental Approach (including methods and authentication of key biological and/or chemical resources, if applicable)
- Responsiveness to the terms of this RFA
- Probability of future NIH funding

A summary of the reviewers' comments will be provided once the review process has been completed.

Award Process

CFAR will notify selected investigators via email within approximately 3-4 weeks of the application deadline. Funding will not be released until all UR and NIH regulatory requirements have been met including IRB, IBC and IACUC approvals as applicable. Upon receipt of all required documentation, the CFAR will issue a formal internal Notice of Award.

Reporting Requirements

The pilot PI will be required to present the status of the pilot project work to the CFAR Steering or Mentoring Committee.

CFAR is required to report the outcome of this award to NIH for a period of no less than 5 years. Routine reporting is thus required of the investigator and should be comprised of a written report, which must include the following:

- Status of the work supported by pilot grant
- Statement regarding resulting grant applications, publications, presentations and inventions
- Update regarding plans for future funding resulting from the project

Awardees may also be asked to present their projects and results at a CFAR sponsored event and/or annual World AIDS Day Scientific Symposium.

Inquiries:

CFAR Director – Steve Dewhurst
CFAR co-Director – Mike Keefer
CFAR Pharmacology Shared Resource – Gene Morse
CFAR Administrator – Laura Enders
P: 585-273-2939
F: 585-473-9573
http://www.urmc.rochester.edu/cfar/

CFAR Pharmacology Shared Resource
Director: Gene D. Morse, PharmD; Associate Director: Charles Venuto, PharmD

The Pharmacology Shared Resource is a multifaceted resource that facilitates clinical and translational pharmacology research among CFAR investigators. The Pharmacology Shared Resource has been conducting antiretroviral pharmacology research since the beginning of the HIV epidemic and was one of the initial Pharmacology Specialty Laboratories funded at the University of Rochester Clinical Trials Unit when the NIH AIDS Clinical Trials Group (ACTG) was established. The Shared Resource Director, Gene D. Morse, is a Board Certified Pharmacotherapy Specialist and directs this New York State-approved pharmacology laboratory. The Pharmacology Shared resource is a training site for numerous national and international faculty, pre-doctoral students, post-doctoral fellows and residents. Dr. Morse is the current Director of the ACTG Pharmacology Core in the Laboratory Center Network and is a member of the Viral Reservoirs and Eradication Transformative Science Group and the Chair of the ACTG Clinical Pharmacology Advisory Group. The Pharmacology Shared Resource is a recognized international leader in HIV Clinical Pharmacology research and training and currently receives NIH funding for the NIAID HIV Clinical Pharmacology Quality Assurance Program, an AIDS Clinical Trials Group Pharmacology Specialty Laboratory and an HIV Research Training Program in Clinical Pharmacology in Zimbabwe from the NIH Fogarty International Center. The Pharmacology Shared resource provides services to CFAR investigators that include pre-clinical and clinical study design and analysis for pharmacokinetics, pharmacodynamics and pharmacogenomics as well as drug assays, drug interactions, therapeutic drug monitoring and nanopharmacology research.

Pharmacology Shared Resources:

Pre-clinical Pharmacology

- ☐ New drug assay development
- ☐ Approved drug assays: TDF, EMT, ABC, LMV, NNRTIs, HIV-1 protease inhibitors, integrase inhibitors
- ☐ HCV DAAs
- ☐ Data analysis for dose finding and animal pharmacokinetics
- ☐ Tissue drug distribution, (CNS, hepatic, GALT)
- ☐ Formulation testing, pharmacokinetic analysis for bioavailability studies
- ☐ Non-compartmental and compartmental pharmacokinetic data analysis
- ☐ PK-PD analysis and modeling
- ☐ Nanoparticle development, release kinetics, tissue targeting, cellular PK

Clinical Pharmacology

- ☐ Drug assay development
- ☐ Approved drug assays: TDF, EMT, ABC, LMV, NNRTIs, HIV-1 protease inhibitors, integrase inhibitors
- ☐ HCV DAAs
- ☐ Phase I Pharmacokinetic-Pharmacodynamic studies, tissue drug assay development
- ☐ Pharmacokinetic drug interaction study design, drug assay development and validation, Pharmacokinetic analysis
- ☐ Non-compartmental and compartmental pharmacokinetic data analysis
- ☐ Nanoformulation testing, cell targeting nanoparticles
- ☐ New drug development: Phase I-IV Pharmacokinetic-Pharmacodynamics, compartment distribution and modeling

CFAR Checklist (to be included with proposal):

- ☐ Completed CFAR Proposal Packet with Checklist indicating submitted items (to be submitted as part of the combined PDF)
- ☐ CFAR Proposal sign-off form (see bottom of these guidelines for printable version)
- ☐ Draft Cost Sharing form signed by PI and department (fully signed forms will be required for pilots selected for funding). See UR ORPA website for the form. Contact Laura Enders for more information or a blank form.
- ☐ CFAR Grant Cover Sheet - Modified PHS 398 face page
- ☐ Abstract
- ☐ Identification of the **CFAR RFA Research Topic** that this application will focus on (see RFA Specific Areas of Interest)
- ☐ Identification of the **High Priority Research Topic** that this application will focus on (see NIH HIV/AIDS Research Priorities list as designated by NIH and OAR included in these guidelines)
- ☐ NIH-format biosketch for PI, co-investigators and mentors
- ☐ Updated Other Support for PI's only
- ☐ Research Plan (limited to 3 pages):

  The Research Plan consists of items noted below, as applicable. It should be self-contained and include sufficient information to evaluate the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.

  - Specific Aims
  - Research Strategy (Significance, Innovation and Approach)
  - Timeline
  - Source of samples
- ☐ Human Subjects and Animals (no limit):

  The Human Subjects and Animals Plan consists of items noted below, as applicable. It should be self-contained and include sufficient information to evaluate the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.

  - Protection of Human Subjects
  - Vertebrate Animals
- ☐ Plans for Future Funding (limited to 1 page):
  - Provide a short outline of how the pilot will develop into a NIH-funded grant. It should include the proposed hypothesis and specific aims intended for a NIH grant application as well as the projected timeline for submission.
- ☐ Pharmacology Shared Resource Request Sheet (if applicable)
- ☐ CFAR Analysis Plan (half-page limit):
  - Provide a brief data analysis plan and identify if bioinformatics support is needed for data collection and management.
- ☐ Draft Cost Sharing form signed by PI and department (fully signed forms will be required for pilots selected for funding). See UR ORPA website for the form.
- ☐ Mentoring Plan (if applicable):
  - Identify a primary mentor and provide a clearly delineated mentoring plan, including frequency and methods. The plan should identify long-term needs and goals in order to establish a successful independent academic career within the next 2 to 5 years.
- ☐ Budget (limited to 1 page using PHS 398 Form Page 4, providing a detailed description of supplies and other expenses within the form page):
  - Limited to **$10,000** direct costs.
  - Earliest start date 8/1/17, end date must be 4/30/18.
  - Unless exceptional circumstances, funds may not be used to support faculty salary but the budget must identify the proposed effort.
  - Funds may not be used for travel to professional meetings or equipment.
  - Funds may be used to support research supplies and expenses, travel to collect data and other non-faculty salary.
  - If applicable, identify other sources of support that will be used to complete the pilot project.
- ☐ Bibliography

Pharmacology Shared Resource Request Sheet

Pre-clinical Pharmacology

- ☐ New drug assay development
- ☐ Approved drug assays: TDF, EMT, ABC, LMV, NNRTIs, HIV-1 protease inhibitors, integrase inhibitors
- ☐ HCV DAAs
- ☐ Data analysis for dose finding and animal pharmacokinetics
- ☐ Tissue drug distribution, (CNS, hepatic, GALT)
- ☐ Formulation testing, pharmacokinetic analysis for bioavailability studies
- ☐ Non-compartmental and compartmental pharmacokinetic data analysis
- ☐ PK-PD analysis and modeling
- ☐ Nanoparticle development, release kinetics, tissue targeting, cellular PK

Clinical Pharmacology

- ☐ Drug assay development
- ☐ Approved drug assays: TDF, EMT, ABC, LMV, NNRTIs, HIV-1 protease inhibitors, integrase inhibitors
- ☐ HCV DAAs
- ☐ Phase I Pharmacokinetic-Pharmacodynamic studies, tissue drug assay development
- ☐ Pharmacokinetic drug interaction study design, drug assay development and validation, Pharmacokinetic analysis
- ☐ Non-compartmental and compartmental pharmacokinetic data analysis
- ☐ Nanoformulation testing, cell targeting nanoparticles
- ☐ New drug development: Phase I-IV Pharmacokinetic-Pharmacodynamics, compartment distribution and modeling

Information about HIV/AIDS Research Priorities and Guidelines for Determining AIDS Funding

NIH HIV/AIDS Research Priorities and Guidelines for Determining AIDS Funding
Notice Number: NOT-OD-15-137
Key Dates
Release Date: August 12, 2015
Related Announcements
NOT-HL-15-281
NOT-HL-15-280
Issued by
National Institutes of Health (NIH)
Office of AIDS Research (OAR)

Purpose:
The NIH supports a comprehensive portfolio of biomedical, behavioral, and social science research on HIV and its associated coinfections, comorbidities, and other complications. The Office of AIDS Research (OAR), a component of the NIH Office of the Director, is legislatively mandated to coordinate, plan, evaluate, and budget for the NIH AIDS research program. Building on the most recent scientific progress and scientific opportunities to most likely contribute to ending the AIDS pandemic, developing a cure for HIV/AIDS, and achieving an AIDS-free generation, NIH has identified the highest HIV/AIDS research priorities for the next 3-5 years. NIH will use these guidelines to ensure that AIDS resources are supporting the highest HIV/AIDS research priorities. The overarching NIH HIV/AIDS research priorities are: 1) research to reduce the incidence of HIV/AIDS, including the development of safe and effective HIV/AIDS vaccines; 2) development of the next generation of HIV therapies with improved safety and ease of use; 3) research towards a cure for HIV/AIDS; and 4) HIV-associated comorbidities and co-infections. Basic research, health disparities, and training that cross-cut these priorities also will be supported. These priorities were informed by the OAR Advisory Council's recommendations, the Annual Trans-NIH Plan for HIV-Related Research, and input from NIH leadership. Implementation of these priorities will begin with fiscal year 2016 funding of HIV/AIDS research.

The NIH has developed a series of guidelines for determining whether a research project has a high-, medium-, or low-priority for receiving AIDS-designated funding. These guidelines do not assess/determine the scientific and technical merit of a project only the priority for receiving AIDS-designated funds. A description of these priority topics and examples of each are provided below.

High Priority topics of research for support using AIDS-designated funds

- Reducing Incidence of HIV/AIDS including: developing and testing promising vaccines, developing and testing microbicide and pre-exposure prophylaxis candidates and methods of delivery, especially those that mitigate adherence issues; and developing, testing, and implementing strategies to improve HIV testing and entry into prevention services.
- Next generation of HIV therapies with better safety and ease of use including: developing and testing HIV treatments that are less toxic, longer acting, have fewer side effects and complications, and easier to take and adhere to than current regimens. Additionally, implementation research to ensure initiation of treatment as soon as diagnosis has been made, retention and engagement in these services, and achievement and maintenance of optimal prevention and treatment responses.
- Research toward a cure including: developing novel approaches and strategies to identify and eliminate viral reservoirs that could lead toward a cure or lifelong remission of HIV infection, including studies of viral persistence, latency, reactivation, and eradication.
- HIV-associated comorbidities, coinfections, and complications including: addressing the impact of HIV-associated comorbidities, including tuberculosis, malignancies; cardiovascular, neurological, and metabolic complications; and premature aging associated with long-term HIV disease and antiretroviral therapy.
- Cross cutting areas: Basic research, health disparities, and training including:
- Basic Research: understanding the basic biology of HIV transmission and pathogenesis; immune dysfunction and chronic inflammation; host microbiome and genetic determinants; and other fundamental issues that underpin the development of high priority HIV prevention, cure, co-morbidities, and treatment strategies.
- Research to Reduce Health Disparities in the incidence of new HIV infections or in treatment outcomes of those living with HIV/AIDS.
- Research Training of the workforce required to conduct High Priority HIV/AIDS or HIV/AIDS-related research.

Further information can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-137.html

Grant Application
UR CFAR Grant Cover Sheet

1a. TITLE OF PROJECT

2a1. PRINCIPAL INVESTIGATOR (INSTITUTION 1)	2b1. DEGREE(S)	2c1. NEW INVESTIGATOR ☐ No ☐ Yes
2d1. POSITION TITLE	2e1. DEPARTMENT, MAJOR SUBDIVISION (if applicable)	
2f1. TELEPHONE TEL ext: Email:	2g1. MENTOR	
2a2. PRINCIPAL INVESTIGATOR (INSTITUTION 2)	2b2. DEGREE(S)	2c2. NEW INVESTIGATOR ☐ No ☐ Yes
2d2. POSITION TITLE	2e2. DEPARTMENT, MAJOR SUBDIVISION (if applicable)	
2f2. TELEPHONE TEL ext: Email:	2g2. MENTOR	

3. ADDITIONAL INVESTIGATORS (if applicable)	
NAME	DEPARTMENT, MAJOR SUBDIVISION (if applicable)

4a. HUMAN SUBJECTS RESEARCH ☐ No ☐ Yes	4b. RESEARCH EXEMPT ☐ No ☐ Yes If yes, exemption #
4c. STATUS OF IRB SUBMISSION/APPROVAL ☐ Approved ☐ Submitted, review pending ☐ Not yet submitted	4d. CLINICAL TRIAL ☐ No ☐ Yes

5a. VERTEBRATE ANIMALS ☐ No ☐ Yes	5b. STATUS OF IACUC SUBMISSION/APPROVAL ☐ Approved ☐ Submitted ☐ Not yet submitted

6a. BIOHAZARD SAFETY Will the project use any materials that would require IBC approval: ☐ No ☐ Yes	6b. HUMAN EMBRYONIC STEM CELL ☐ No ☐ Yes

7a. PROPOSED PROJECT PERIOD	7b. FUNDS REQUESTED (Direct Costs)	7c. PROPOSED SUBCONTRACT ☐ No ☐ Yes

CFAR PROPOSAL SIGN-OFF FORM

THIS FORM MUST BE COMPLETED AND SUBMITTED TO THE UR-CFAR WITH YOUR PILOT PROPOSAL AFTER ALL NECESSARY SIGNATURES HAVE BEEN OBTAINED. THIS FORM DOES NOT NEED TO BE SUBMITTED TO ORPA.

Principal Investigator (PI)/Contact PI _____ UR Financials Company 040 UR Financials Cost Center CC 12193-000 (DCFAR)

Please check if this is a Multiple PI project (as defined by NIH

Other Multiple PIs/Co-PIs: _____ Project Sponsor CFAR

Project Title _____

Funding Op (Number/Title) _____ Award mechanism (R01, K08, CAREER) _____

Proposed Start Date _____ End Date _____ Total Project Budget Requested _____ Deadline _____

Proposal Type: ☐ New ☐ Continuation ☐ Supplement ☐ Resubmission ☐ Renewal Current UR Financials FAO (if applicable): GR _____

F&A (Indirect) Rate _____ Award Type: ☐ Grant ☐ Contract ☐ Subcontract/subaward

Purpose: ☐ Research ☐ Clinical Research ☐ Training ☐ Fellowship ☐ Service ☐ Other

Project Location: ☐ On-Campus ☐ Off-Campus If off-campus, location _____

ADMINISTRATIVE AND POLICY CONSIDERATIONS (MUST BE COMPLETED BY PI) - Please explain "yes" responses on additional sheets

NOTE: All Co-Investigators, and other named investigators, MUST complete Section A ("Additional Signatures Certification")

Yes	No		
☐y	☐n	1.	Does this project contain a clinical research component with clinical procedures? If "Yes", complete Section B (on page 4).
☐y	☐n	2.	Does this project require additional/new space or renovation/modification of current space or facilities? Check all that apply: Equipment/Utility support _____ Additional, New or Renovated Space _____ If yes, include an explanation on amount of space needed, cost and source of funds.
☐y	☐n	3.	Does this proposal involve cost sharing or matching funds? If yes, complete below: -Total Amount of cost sharing _____ -Type of cost being shared _____ -Planned cost share UR Financials FAO(s) _____ -If the cost sharing is **Third Party Cost Sharing**, attach a Pre-award THIRD PARTY COST SHARING FORM
☐y	☐n	4.	Will research use human subjects?
☐y	☐n	5.	Will research use animals?
☐y	☐n	6.	Will research use radioactive materials or isotopes?
☐y	☐n	7.	Will research use human embryonic stem cells?
☐y	☐n	8.	Are you requesting less than the maximum F&A costs as allowed by the sponsor's written policy?
☐y	☐n	9.	Will there be subcontracts to other institutions? Number? _____
☐y	☐n	10.	Is any program income anticipated under this project?
☐y	☐n	11.	Do you have consulting arrangements, line management responsibilities, substantial equity holdings with the sponsor, subcontractor, or potential vendor?
☐y	☐n	12.	Have you submitted an annual conflict of interest disclosure statement?

Yes	N/A		
☐y	☐n	13.	If you have acquired new financial interests since your last disclosure, have you reported these to the institution?

Yes	No		
☐y	☐n	14.	For NIH proposals, do all investigators agree to comply with the NIH Public Access Policy? Please see the NIH Policy for details.
☐y	☐n	15.	Is this an Individual NRSA (F-awards) Fellowship? If yes, complete the Individual Fellow and Faculty Mentor Certification for NIH F-awards Certification Individual Fellow and Faculty Mentor Certification for NIH F-awards.
☐y	☐n	16.	Are you currently debarred or suspended from doing business with the federal government or excluded from Medicare or other federal/state health care programs, or are you currently in default on any federal student loans?
☐y	☐n	17.	Have you engaged in lobbying activities using federal funds to influence any federal employee in connection with this proposal?
☐y	☐n	18.	If funded, will other individuals be authorized to sign for purchases necessary for the project? If yes, name authorized individuals: _____
☐y	☐n	19.	Is this proposal a collaborative inter-school/college program with sharing of indirect cost recovery? If yes, attach completed copy of Sharing of Indirect Cost Recovery form.
☐y	☐n	20.	Does the project involve international partnerships or activities in foreign countries? Country name: _____
☐y	☐n	21.	Will the work involve the transfer of technology and/or materials overseas?
☐y	☐n	22.	Identify the CLASP-certified individual(s) who will have functional responsibility for oversight of this project, should it be funded. _____ (Signature or initials of this individual recommended)

PRINCIPAL INVESTIGATORS' CERTIFICATION

In signing below the Principal Investigator(s) (PIs) certify that the above is accurate and complete to the best of the PIs' knowledge. ***This certification must also include signatures of all investigators in Section A (page 3 of this form).*** *The PI certifies the proposal (including any subsequent supplemental material) is compliant with sponsor requirements. In addition, the PI(s) understand that any false, fictitious, or fraudulent statements or claims made in the accompanying submission may subject the PI(s) personally to criminal, civil, or administrative penalties. The PI(s) agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.*

Principal Investigator(s): _____ Date: _____

REQUIRED SIGNATURES: (PLEASE SEE REVERSE FOR ADDITIONAL SIGNATURES WHICH MAY BE REQUIRED)

Dept Chair: _____ Date: _____

Dean: _____ Date: _____

Cost Center Chief: _____ Date: _____

Director of Medical Center Space Planning: _____ Date: _____
(required for Medical Center if "Yes" has been checked on consideration 2 above)

Form Rev 01/01/15 **For ORPA use only:**

ORPA RA: _____ Date: _____

OBTAIN FOLLOWING SIGNATURES AS APPLICABLE TO THIS PROPOSAL:

Yes **No**

☐y ☐n A. Is proposed project using space or facilities of Strong Memorial Hospital? If yes, obtain Signature of SMH Senior Director for Finance (x5-3033 – Room 1-2412): _____

☐y ☐n B. Will project require resources of the University Vivarium? If yes, please list the animal species _____and the estimated maximum number of each species housed at one time _____and send a copy of the signoff form to the attention of the Vivarium Director, Box 674.

☐y ☐n C. Will project require resources of the CRC? If yes, obtain Signature of CRC Director:

_____

☐y ☐n D. Will project require services of the Department of Biostatistics and Computational Biology? If yes, obtain Signature of Chair, Department of Biostatistics and Computational Biology:

_____

☐y ☐n E (a). Will this project include pathogens, recombinant DNA, human blood, body fluids or tissue, virus vectors, human cell lines or generation of transgenic animals via recombinant DNA technology or interbreeding? For additional information, consult the IBC Webpage.

☐y ☐n E (b). Will this project involve an OSHA recognized carcinogen? (2-Acetylaminofluorene, 4-Aminodiphenyl, Benzidine, bis-Chloromethyl ether, 3,3'-Dichlorobenzidine (and its salts), 4-Dimethylaminoazo-benezene, Ethyleneimine, methyl chloromethyl ether, alpha-Naphthylamine, beta-Naphthylamine, 4-Nitrobiphenyl, N-Nitrosodimethylamine, beta-Propiolactone)

If answer to question E(a) or E(b) is marked "Yes", please send a copy of this completed signoff form to the attention of the IBC Program Coordinator, Environmental Health & Safety, RC Box 278878.

☐y ☐n F. Will faculty or staff from other University departments, divisions, or units participate in this project or will resources of another department, unit or office (**see below**) be used? If yes, obtain signature of Participating Department Chair(s), Dean(s), or Director(s):

Faculty and Dept. Name (printed)	**Signature**
Faculty and Dept. Name (printed)	**Signature**
Faculty and Dept. Name (printed)	**Signature**

DESCRIPTION OF PROPOSAL SIGN-OFF RESPONSIBILITIES

PRINCIPAL INVESTIGATOR/MULTIPLE PI: The PI/Multiple PI is the initiator and director of the proposed program. The PI's/Multiple's PIs' signature(s) indicates that he/she/they will adhere to University and sponsor policies affecting the project, including completion of an Employee Intellectual Property Agreement and conflict of interest disclosure, monitoring of expenditures and the submission of reports required by the sponsor and the University.

DEPARTMENT CHAIR, DIVISION/UNIT CHIEF: These signatures mean that agreement has been reached regarding the amount and type of departmental resources that will be required to assist a PI in completing a project. If new space, personnel, or renovations are required, further discussion with the appropriate Dean's office will be necessary. This signature also confirms receipt of the annual conflict of interest disclosure and, where required, the supplemental disclosure and certifies that review will be complete and conflicts resolved, if any, prior to award.

DEAN: The Dean's signature means that agreement has been reached regarding the amount of School/College resources required to support the program. The Dean ensures that appropriate salary and pooled costs are requested in the proposal. As well, the Dean participates in discussions of new space or renovations required to complete a project.

THIRD PARTY COST SHARING: A complete Pre-Award Third Party Cost Sharing is required at the time of proposal to indicate the Third Party's concurrence with their cost sharing responsibilities.

ADDITIONAL REVIEW AND/OR OTHER SIGNATURES WHICH MAY BE REQUIRED DEPENDING UPON THE NATURE OF THE RESEARCH:

RESOURCES OF OTHER DEPARTMENTS, UNITS OR OFFICES: Projects that require resources of other University departments or offices require approval of the appropriate signatory. At the Medical Center, examples include Blackboard Online Learning, Curricular Affairs/Office of Medical Education, etc.

VIVARIUM: All University projects using animals must be reviewed by the University Committee of Animal Resources (UCAR, x5-1693).

BIOHAZARDS: Projects which propose the use of potential biohazards, including recombinant DNA and carcinogens, must be reviewed by the Executive Secretary of the Biosafety Committee, 685 Mt Hope Ave., x5-3241. This signature is required to comply with federal and state regulations covering biohazards.

BIOSTATISTICS AND COMPUTATIONAL BIOLOGY SERVICES: Projects that involve biostatistics services must be approved by the Department of Biostatistics and Computational Biology, Saunders Research Bldg. Room 4106, x5-2407. This signature ensures that adequate costs and professional effort have been included to support biostatistical studies.

STRONG MEMORIAL HOSPITAL: Projects which involve facilities, services, or training programs of Strong Memorial Hospital require the signature of the Senior Director for Finance, Room 1-2412, Medical Center, x5-3300.

CLINICAL RESEARCH CENTER: Projects which will require beds, space, or staff of the Clinical Research Center should be reviewed by the Director of the Clinical Research Center. Room 1.502, Saunders Research Building, x5-0674.

EXPLANATION OF THE ITEMS FROM FRONT (use additional sheets)

Section A: Additional Signatures Certification
new, competing, and non-competing (progress reports) applications

In signing below the following Investigators certify that:

- they have submitted an annual conflict of interest disclosure statement;

- there are no new financial interests to report (if there are new financial interests that have not been disclosed, the investigator must report these prior to proposal submission); and

- they are not currently debarred or suspended from doing business with the federal government or excluded from Medicare or other federal/state health care programs, or that they are not currently in default on any federal student Loans.

- In addition, the Investigators understand that any false, fictitious, or fraudulent statements or claims made in the accompanying submission may subject the Investigators personally to criminal, civil, or administrative penalties. The Investigators agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

Name	**Signature**	**Role on Project** ***(e.g. PI, Res. Assoc.)***

SECTION B: Prospective Reimbursement Analysis (PRA) (Note 1)

If Question 1 in the **ADMINISTRATIVE AND POLICY CONSIDERATIONS** section was answered "Yes", please check one of the appropriate boxes below:

☐y The clinical research study's clinical procedures constitute a clinical trial (i.e. there is an investigational drug, device or treatment). ***The PI has signed the following three (3) worksheets (copies are attached to this sign off form): PRA Template, Participant Grid/Billing Plan and Total Budget comparison worksheet (refer to Note 2 and Note 3).***

☐y The clinical research study's clinical procedures constitute a clinical trial (i.e. there is an investigational drug, device or treatment) and the sponsor has indicated it will pay for all visits and procedures (i.e. nothing will be billed to third party insurance). ***The PI has signed the following two (2) worksheets (copies are attached to this sign off form): Participant Grid/Billing Plan and Total Budget comparison worksheet (refer to Note 3).***

☐y The clinical research study is not a clinical trial (i.e. there is not an investigational drug, device or treatment). ***The PI has signed the following two (2) worksheets (copies are attached to this sign off form): Participant Grid/Billing Plan and Total Budget comparison worksheet (refer to Note 3).***

PRINCIPAL INVESTIGATORS' CERTIFICATION

In signing below the Principal Investigator(s) certify that he/she has completed the Blackboard clinical trial training (Course CT-01).

_____ *Date:* _____

Principal Investigator(s) Name(s)

NOTE 1: The University of Rochester Clinical Research Standard Operating Procedures Regarding Financial Oversight and Billing Compliance defines a Prospective Reimbursement Analysis as "the process of determining and documenting what procedures, items and tests in a protocol are standard of care or strictly related to research. This information is then used to determine the appropriate payer of such activities" (SOP 1.1).

NOTE 2: The PRA Template is a questionnaire that assists with the determination whether a clinical trial is a "Qualifying trial" as per Centers for Medicare and Medicaid Services guidelines. The PRA Template is a worksheet within the UR's Budgeting Workbook for clinical trials, accessible in the Clinical Trial Resources Share Point site (that is accessible through the link on this web page http://www.rochester.edu/ORPA/Clinical_Trial_Resources/index.html).

NOTE 3: The Participant Grid/Billing Plan is an EXCEL worksheet on which is documented the proper payer for each clinical procedure for each visit in a clinical research study plan. A Total Budget comparison worksheet allows comparison of the sponsor's financial offer to the UR's internally prepared budget and indicates whether a potential deficit or surplus exists. . The Participant Grid/Billing Plan and the Total Budget comparison are worksheets within the UR's Budgeting Workbook for clinical trials, accessible in the Clinical Trial Resources Share Point site (that is accessible through the link on this web page: http://www.rochester.edu/ORPA/Clinical_Trial_Resources/index.html).

UNIVERSITY OF ROCHESTER
PROPOSED COST SHARING COMMITMENT FORM

Note that this form must be completed for all mandatory cost sharing, regardless of whether the proposal is for research, training or other sponsored activities. It also must be completed for all voluntary committed cost sharing pledged for a research proposal, with the exception of: a) proposals indicating effort on NIH career awards that overlaps with other federal awards and b) effort reported on private foundation awards where there is overlap with other federal awards.

Investigator:_____ Sponsor: _____

Proposal Title:_____

1. University Cost Sharing

Type of Cost-Sharing: **Voluntary ☐** **Mandatory ☐**

If voluntary, please explain the necessity for University cost sharing

Category (Identify Personnel by Name)	**Year 1 Dates** _____ **to** _____	**Year 2 Dates** _____ **to** _____	**Year 3 Dates** _____ **to** _____	**Year 4 Dates** _____ **to** _____	**Year 5 Dates** _____ **to** _____	**Source of Cost Sharing: Company (CM040) Cost Center (CC11475000 FAO (OPxxxxxx)**
(If dates of cost sharing are less than full budget year, please indicate)						
Personnel Effort						
						CM CC OP
						CM CC OP
Staff Benefits @ 0.00% 0.00%						**CM CC OP**
Tuition						**CM CC OP**
Equipment						**CM CC OP**
Other direct costs (Specify)						**CM CC OP**
Total Direct Cost	$ 0	$ 0	$ 0	$ 0	$ 0	
Indirect Cost @ 0.00%						**CM CC OP**
Total University Cost Sharing	$ 0	$ 0	$ 0	$ 0	$ 0	

Total Cost Sharing Contribution $ 0

Total Project Costs (Including University Cost Share Funds) $ _____

II. Third Party Cost Sharing (Attach supporting documentation: see instructions)

Organization	Amount of Cost Sharing	Source of Cost Sharing

III. Related University Cost Share FAOs

FAO	Principal Investigator	Title of Project/FAO Designation

Certification by Principal Investigator

I certify that the costs and/or FAO(s) stated above represent costs and/or projects directly related to the work statement of the named proposal/project, and represent allowable cost sharing.

_____
Principal Investigator Date

Approved

_____ _____ _____
Chair Date Dean Date ORPA Date

Instructions to Proposed Cost Sharing Commitment Form (ORPA Form 150)

Section I: University Cost Sharing

1) The proposed University cost share budget must be completed by category. The budget should reflect the budget identified in the proposal to the sponsoring agency.
2) If applicable, proposed University personnel costs must be identified by individual(s) and percentage of time devoted to the project.
3) The source of cost sharing must be completed. The source may be identified by: a) University departmental FAO (if known); b) approved Department or Dean's Office FAOs; c) waiver of indirect costs. All waivers must be discussed and approved by the appropriate University Dean's Office.

Section II: Third Party Cost Sharing

If cost sharing is proposed by third-party sources, (i.e. the University is not a contributor), Section II must be completed. The organization providing cost sharing must be named and its respective contribution identified; verification of third party cost sharing should be provided by either the **Third Party Cost-Sharing Form** or a letter committing the organization signed by an authorized official. Subsequent supporting documentation must adhere to the University of Rochester Policy and Procedures for the Administration of Cost Sharing.

Section III: Related University Cost Share FAOs

If cost sharing is proposed by use of another University FAO in total, Section III must be completed. The technical relationship between the two (or more) projects must be established. The FAOS must be identified and the PI must certify to their relatedness. Please note that other Federal projects may not be used for cost sharing in proposals to Federal agencies, unless specifically approved by the sponsor.